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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,723	12/15/2005	Richard Einstein	BJS-3665-166	5102
23117 7590 11/28/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER AEDER, SEAN E	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/560,723		EINSTEIN ET AL.	
	Examiner		Art Unit	
	Sean E. Aeder		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 16, 17, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 16, 17, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 2 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The Amendments and Remarks filed 10/10/07 in response to the Office Action of 4/10/07 are acknowledged and have been entered.

Claims 1-3, 16, 17, 32, and 33 are pending.

Claims 1-3, 16, and 32 have been amended by Applicant.

Claims 1-3, 16, 17, 32, and 33 are currently under examination.

Objections Withdrawn

The objections to claims 1-3, 16, 17, 32, and 33 are withdrawn.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn.

The rejection of claim 2 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn. However, it is noted that claims 1, 3, 16, 17, 32, and 33 remain rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, for the reasons stated below.

The rejection of claim 2 under 35 U.S.C. 102(e), for being anticipated by Gish et al (US 2007/0014801; filed 10/12/01), is withdrawn. However, it is noted that claims 1, 3, 16, 17, 32, and 33 remain rejected under 35 U.S.C. 102(e), for being anticipated by Gish et al (US 2007/0014801; filed 10/12/01), for the reasons stated below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 16, 17, 32, and 33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons stated in the Office Action of 4/10/07 and for the reasons set-forth below.

The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of (1) nucleic acid variants of SEQ ID NO:92 that are at least 95% identical to the nucleic acid sequence set-forth in SEQ ID NO:92 when aligned without allowing for gaps, (2) fragments of a portion of nucleic acids comprising the sequence of SEQ ID NO:2 wherein said fragments are at least 20 nucleotides in length and comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing, (3) fragments of a portion of nucleic acid variants of SEQ ID NO:92 that are at least 95% identical to the nucleic acid sequence set-forth in SEQ ID NO:92 when aligned without allowing for gaps wherein said fragments are at least 20 nucleotides in length and comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing, (4) primers that

Art Unit: 1642

specifically amplify nucleic acid variants of SEQ ID NO:92 that are at least 95% identical to the nucleic acid sequence set-forth in SEQ ID NO:92 when aligned without allowing for gaps, (5) primers that specifically amplify fragments of nucleic acids comprising the sequence of SEQ ID NO:2 wherein said fragments are at least 20 nucleotides in length and comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing, (6) primers that specifically amplify fragments of nucleic acid variants of SEQ ID NO:92 that are at least 95% identical to the nucleic acid sequence set-forth in SEQ ID NO:92 when aligned without allowing for gaps wherein said fragments are at least 20 nucleotides in length and comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing, (7) nucleic acid molecules encoding a polypeptide comprising the sequence of an extracellular domain of a protein encoded by a gene or RNA comprising the sequence of SEQ ID NO:92, and (8) nucleic acid molecules encoding a polypeptide comprising the sequence of an extracellular domain of a protein encoded by a gene or RNA comprising the sequence of SEQ ID NO:92 wherein the polypeptide has 8 to 100 amino acids in length.

The written description in this case sets forth polynucleotide sequences comprising *the* sequence set-forth in SEQ ID NO:92 (see Figure 2, in particular). The specification does not disclose any other fragment or variant of SEQ ID NO:92 as broadly encompassed in the claims. Further, it does not appear that the specification discloses any primer mixtures.

The state of the art is that sequences comprising *the* sequence set forth in SEQ ID NO:92 have not been disclosed in the art. However, a few variants and fragments

Art Unit: 1642

thereof, such as a sequence taught by Gish et al (US 2007/0014801 A1; filed 10/12/01) (see below), can be found in the prior art. In regards to the genera of primer mixtures, the broad genus of primer mixtures that would specifically amplify all of the broadly recited sequences are not found in the art. However, a few primer mixtures, such as the primer mixtures taught by Gish et al (see below), can be found in the prior art.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of sequences that encompass the genera nor does it provide a description of structural features that are common to the genera. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because

the genera are highly variant, the disclosure of SEQ ID NO:92 is insufficient to describe the genera. Further, in regards to genera encompassing variants, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (<http://www.uspto.gov/web/menu/written.pdf>), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genera and therefore conception is not achieved until reduction to practice has occurred, regardless

Art Unit: 1642

of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In the Reply of 10/10/07, Applicant argues that the disclosure supports the presently claimed genus. Applicant further states that one of ordinary skill in the art would appreciate that applicants were in possession of the claimed invention at the time the application was filed.

The amendments to the claims and the arguments found in the Reply of 10/10/07 have been carefully considered, but are not deemed persuasive. In regards to the argument that the disclosure supports the presently claimed genus, the disclosure does not provide a written description demonstrating that applicants were in possession of the broadly claimed genera at the time the application was filed for the reasons stated above and in the Office Action of 4/10/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 16, 17, 32, and 33 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gish et al (US 2007/0014801 A1; filed 10/12/01) for the reasons stated in the Office Action of 4/10/07 and for the reasons set-forth below.

Claim 1 encompasses fragments of nucleic acid variants of SEQ ID NO:92 that are at least 95% identical to a portion of the nucleic acid sequence set-forth in SEQ ID NO:92 when aligned without allowing for gaps wherein said fragments are at least 20 nucleotides in length and comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing (see part iii). Claim 3 is drawn to a primer mixture that specifically amplifies a nucleic acid of claim 1. Claim 16 is drawn to a diagnostic kit for detection of prostate cancer which comprises a nucleic acid according to claim 1 and a detectable label. Claim 17 is drawn to a diagnostic kit for detection of prostate cancer which comprises primers according to claim 3 and a diagnostically acceptable carrier. Claim 32 is drawn to a nucleic acid molecule encoding a polypeptide comprising the sequence of an extracellular domain of a protein encoded by a gene or RNA comprising

Art Unit: 1642

the sequence of SEQ ID NO:92. Claim 33 is drawn to the molecule of claim 32, wherein said polypeptide has 8 to 100 amino acids in length.

Gish et al teaches a nucleic acid sequence that is expressed by human prostate cancer cells, SEQ ID NO:271, which is a 1365 nucleotide variant of instant SEQ ID NO:92 that is >99% identical to a 1365 nucleotide fragment of instant SEQ ID NO:92 when aligned without allowing for gaps (see paragraph 7 and attached sequence comparison, in particular). As evidenced by the Reply of 10/10/07, the nucleic acid sequence taught by Gish et al comprise an exon-exon, exon-intron, or intron-intron junction sequence generated by splicing (see bottom alignment of the sequence taught by Gish et al and the sequence of STEAP-2, in particular). It is further noted that SEQ ID NO:271 comprises fragments of instant SEQ ID NO:92 greater than 20 nucleotides in length. Gish et al further teaches a primer mixture comprising primers that specifically amplify SEQ ID NO:271 (see paragraph 190, in particular). Gish et al further teaches a diagnostic kit comprising SEQ ID NO:271, a detectable label, and primers that would specifically amplify a polynucleotide comprising SEQ ID NO:271 (see paragraphs 13, 30-32, and 190, in particular). Further, the specification discloses that instant SEQ ID NO:92 is expressed on the extracellular region of a protein (page 11 of the specification, in particular). Therefore, the sequence taught by Gish et al, which comprises sequences encoding 8 to 100 amino acids in length, is a nucleic acid molecule encoding a polypeptide comprising the sequence of an extracellular domain of a protein encoded by a gene or RNA comprising the sequence of instant SEQ ID NO:92.

Art Unit: 1642

In the Reply of 10/10/07, Applicant provides sequence alignments illustrating differences between SEQ ID NO:92 of Gish et al and various STEAP splice variants. Applicant further indicates that the claimed polynucleotides are novel and differ from the sequence taught by Gish et al.

The amendments to the claims and the arguments found in the Reply of 10/10/07 have been carefully considered, but are not deemed persuasive. In regards to statements that the claimed polynucleotides are novel and differ from the sequence taught by Gish et al, the claimed polynucleotides are encompassed by the pending claims for the reasons stated above. It is noted that the pending claims are not limited to the STEAP splice variants illustrated in the Reply of 10/10/07.

Claim Objections

Claim 2 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 32 is objected to because of an apparent typographical error. Claim 32 ends with two periods. Appropriate correction is required to delete one of the periods.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a). A shortened statutory period for response to this Final Action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this Final Action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. '1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than six months from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SEA

/Misook Yu/
Primary Examiner, Art Unit 1642